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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,967	12/31/2001	Wilhelmus Evergardu Hennink	313632001000	8024
25225	7590	07/19/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/913,967	<b>Applicant(s)</b> HENNINK ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of request continued examination under 37 CFR 1.114 and remarks filed 4/27/06. Examiner further acknowledges receipt of declarations filed under 37 CFR 1.132 on 4/27/06; and summary of the interview held with applicant on May 3, 2006. Claims 1-17 and 21-26 are pending. No claim amendment was submitted.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2) 119-140, submitted on form PTO-1449).

Okihara discloses a stereocomplex mixture poly(L-lactide) and poly(D-lactide) and the mixture comprises equimolar amounts of the L- and D-lactide forms (abstract and page 120, paragraph 1). The mixture inherently forms hydrogel. Regarding instant claims 3-5, 8-10 and 13, the stereocomplex of Okihara would inherently have the instant property since the property of a composition cannot be separated from the composition. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Response to Arguments***

3. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive.

Regarding applicants' argument that the claimed invention covers a hydrogel, it is noted that Example 6 of applicants' specification confirms a hydrogel for Okihara.

4. Claims 1-10, 14 and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170, cited on form PTO-1449).

Hennink discloses a biodegradable hydrogel that contains hydrolysable bonds and where the hydrogel consists of two interpenetrating polymer networks interconnecting to one another through hydrolysable spacers (abstract). In Hennink, (poly)glycolic acid and/or (poly)lactic acid spacers are introduced between polymerizable methacrylate groups and dextran (page 7, lines 24-27 and page 8). The hydrogel is prepared by a radical polymerization in the presence of tertiary amine and persulfate initiator (page 9, lines 14-23). Increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Drugs are loaded onto the hydrogel during polymerization or cross-linking (page 10, lines 24 and 25). The hydrogel of Hennink are applied as microspheres of varying sizes (page 10, lines 26-34). See also examples 1-5 for preparation of hydrogels. The teachings of Hennink meet the limitations of the claims.

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Response to Arguments***

5. Applicants' arguments filed 4/27/06 have been fully considered but they are not persuasive.

Regarding the absence of specific chirality in Hennink, it is noted that the prior art meets the limitation of the oligomers recited in claim 2, which defines the oligomers of claim 1. A racemic molecule has equal components of each component of the opposite chirality. Regarding specific claimed chirality, it is noted that the composition claims do not exclude or include covalent or non-covalent interaction. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). T

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170, cited on form PTO-1449).

Hennink clearly teaches the instant hydrogel composition. Hennink teaches that increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Hennink does not teach a degree of substitution of 3-25 as recited in instant claim 11. There is no

comparable example to demonstrate that a degree of substitution of 3-25 provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a stereocomplex hydrogel that has appropriate degree of substitution since according to the teaching of Hennink degree of substitution is related to how cross-linked the polymer network is. One having ordinary skill in the art would have been motivated to prepare a stereocomplex hydrogel composition with a varying degree of substitution with the expectation of obtaining a hydrogel with the desired cross-linked network.

***Response to Arguments***

8. Applicants' arguments filed 4/27/06 have been fully considered but they are not persuasive.

Regarding applicant's argument that Hennink does not suggest polymers substituted with complementary chiral groups, it is noted that claim 11 is directed to mixtures of lactide polymers.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2)119-140, submitted on form PTO-1449).

Okihara teaches the stereocomplex hydrogel composition of the instant invention except that Okihara is silent on the length of the monomers. There is no comparable example to demonstrate that an average length of 7-15 monomers provided unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a stereocomplex hydrogel composition that comprises any length monomers since Okihara appears to teach all lengths. One having ordinary skill in the art would have been motivated to take a mixture of lactides having the appropriate lengths with the expectation that a

stereocomplex hydrogel will form.

***Response to Arguments***

10. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive.

Regarding applicant's argument that Okihara does not teach a hydrogel, it is noted above that Example 6 of applicant's specification confirms Okihara's stereocomplex as a hydrogel.

8. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. (Macromolecules, 1998, 31:6397-6402, provided by applicants on form PTO-1449) in view of Brannon-Peppas (Int. J. Pharm., 1995, 116:1-9, provided by applicants on form PTO-1449).

De Jong discloses preparation of stereocomplexes homo- or copolymers of D- and L-lactides and further discloses that stereocomplex formation is also observed in blends of L-lactide/s-caprolactone and D-lactide/E-caprolactone (abstract and page 6397). Synthesis of the stereocomplex begins with preparing the oligomer in the presence (2-methoxyethoxyethanol (MEE)) initiator and stannous octoate catalyst (page 6399).

De Jong does not teach incorporating active ingredient in the stereocomplex. However, Brannon-Peppas discloses that copolymers of polylactic acid are drug carriers (abstract). Regarding the sequence or preparing the drug containing hydrogel, selection of any order of the preparation steps in instant claims 15-17 is obvious in the absence of unexpected results showing that the order recited in the claims provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an active ingredient in the hydrogel composition of De Jong since Brannon-Peppas teaches that lactide

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hydrogels can be drug carriers. One having ordinary skill in the art would have been motivated to include active agents in the lactide hydrogel formulation of De Jong with the expectation that the stereocomplex lactide hydrogel would serve as a carrier.

***Response to Arguments***

11. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive.

Regarding applicant's argument that hydrogels do not form in water, it is noted that, applicant prepares stereocomplex gels in organic solvent, see Example 1

The claims are directed to compositions. The oligomers are water soluble as directed by These oligomers or at least some of the claim 1 and claim 2 further defines the oligomers. oligomers recited in claim 2 are some of the oligomers disclosed by the prior art. The difference between De Jong and the claims is that De Jong does not incorporate active agent in the stereocomplex and Brannon-Peppas makes up for that deficiency.

1.132 Declaration by Dr. Wilhelmus Everhardus:

The declaration is not commensurate with the invention in terms of formation of hydrogel **only** in water because applicant's Example 1, for example, is prepared in organic solvent and applicant's examples 1, 2 and 4 appear to contradict Exhibit 3 submitted with the declaration. No claim is allowed.

The references cited in this action have been cited and presented previously to applicants. Therefore, those references are not here further furnished.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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